

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X	:	
ESPERION THERAPEUTICS, INC.,	:	
	:	
Plaintiff,	:	No. 1:23-cv-02568-ER
	:	
-against-	:	
	:	
DAIICHI SANKYO EUROPE GMBH,	:	<u>Oral Argument Requested</u>
	:	
Defendant.	:	
	:	
-----X	:	

**ESPERION THERAPEUTICS, INC.’S REPLY MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION FOR JUDGMENT ON THE PLEADINGS**

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PRELIMINARY STATEMENT

Esperion seeks a declaratory judgment enforcing the plain language of the Agreement: that DSE’s payment obligation is triggered by “a result” of the clinical study that shows “cardiovascular risk reduction” at the contractual thresholds. DSE, in contrast, wants the Court to look anywhere *other than* the plain language of the Agreement. DSE’s opposition floods the Court with extrinsic evidence outside the four corners of the Agreement in an effort to distract the Court from the operative and dispositive contractual language. When DSE does engage with the plain text, it is clear that its arguments have no merit and that judgment should be granted to Esperion on the pleadings.

DSE offers one reason after another why the Agreement does not really mean what it says. It urges the Court to reject the Agreement’s words and instead look to “customs and practices of the pharmaceutical industry” passed from one generation to the next. It contends that the key language—“a result”—does not bear its plain meaning because it is actually an “idiom” and should not be taken literally. And it argues the linchpin of the contract—the only event that could trigger DSE’s milestone payment—is a specific result, MACE-4, that the parties did not even mention anywhere in the 84-page Agreement.

The first page of the parties’ briefs perfectly frames their positions. Esperion says:

The contract requires DSE to pay Esperion \$300 million if Esperion obtains a label that includes an indication for “cardiovascular risk reduction,” and also includes “a result” of the clinical study demonstrating a 20% reduction in cardiovascular risk.

Esperion Motion (“Mot.”) at 1 (quoting Section 9.2 of the Agreement). DSE, in contrast, says the contract requires DSE to pay Esperion \$300 million if

the Study yield[s] the result that Esperion had powered the Study to achieve and [European regulators] ultimately approve[] an expanded label consistent with the Agreement.

DSE Opposition (“Opp.”) at 1 (quoting nothing).

Esperion's interpretation relies upon the Agreement's actual language—"a result." DSE's interpretation relies upon a fictional construct reflecting its wishful thinking—"the result that Esperion had powered the Study to achieve." This Court can easily see which party is asking it to enforce the terms of the Agreement as written and which party is not. Because DSE is desperate to escape the actual words of the contract it signed, it inundates the Court with extrinsic evidence, including study protocols, reports, and websites. Of course, Esperion has its own trove of extrinsic evidence that powerfully confirms its reading of the Agreement. But none of this can be considered. "[A] written agreement that is complete, clear and unambiguous on its face must be enforced according to the plain meaning of its terms, without reference to extrinsic materials outside the four corners of the document." *Goldman v. White Plains Ctr. for Nursing Care, LLC*, 11 N.Y.3d 173, 176 (2008) (citation and internal quotation marks omitted). Enforcing contracts as written provides certainty in the commercial world, as businesses can rest assured that a judge will rule based on what their agreement says, rather than on what one party says it thought it meant, in a lawsuit years after the fact when compliance with the agreement no longer suits its interests.

Declaring the meaning of an unambiguous contract under Rule 12(c) also avoids burdening federal courts with unnecessary proceedings. If a contract says the widgets are to be delivered on Friday, judicial resources are not well spent sifting through competing batches of extrinsic evidence and making credibility calls on witness testimony to decide whether one party believed the widgets were to be delivered on Saturday. And if a contract says "a result" of a study obligates payment, judicial resources are not well spent evaluating outside evidence that the parties meant that only "the result that [one party] had powered the Study to achieve" obligates payment.

When DSE finally gets around to addressing the words of the Agreement, it has nothing persuasive to say. If the parties intended, as DSE now says, to make MACE-4 the *only* triggering

event for the milestone payment, they would have done so. The parties knew the Study would generate many different results, and the English language gave the parties many different ways to express specificity and limitation here: “MACE-4,” “primary endpoint,” “key endpoint,” “no secondary endpoints,” and so on. The parties used some of those exact limiting terms in other sections of the Agreement—but not in Section 9.2. Instead, the parties used broad, general language—including the indefinite article “a,” which for well over a century New York courts have held refers to any one of many possibilities. The parties were represented by sophisticated counsel in negotiating the Agreement, and they were careful and deliberate in their choice of language. That makes this a straightforward case for judgment on the pleadings.

ARGUMENT

I. DSE’s Proffered “Extrinsic Evidence” Cannot Overcome The Agreement’s Plain Language.

DSE’s tactics are transparent. Because DSE realizes it will lose if the Court gives the Agreement a plain-language reading, it devotes page after page to extrinsic evidence—purported industry custom and practice, along with reports and studies that have not been incorporated into the contract—all in the hope of kicking up enough sand that the Court will deem the Agreement ambiguous and allow the case to move ahead to trial.

DSE has put the cart before the horse. The Court cannot consider extrinsic evidence unless it has first determined that the Agreement, on its face, is ambiguous. It is *only* “when a court finds ambiguity in the parties’ written agreement may it look to extrinsic evidence to discern the parties’ intent.” *N.Y. Univ. v. Galderma Lab’ys, Inc.*, 689 F. App’x 15, 16 (2d Cir. 2017) (internal quotation marks omitted). DSE misstates the governing legal standard by claiming all it has to do to survive a Rule 12(c) motion is plead a “plausible defense.” Opp. 9. That is wrong. “Plausibility” is the test for whether the factual allegations in a complaint are legally sufficient to

state a claim for relief. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Here, the question is simply whether the Agreement—on its face and without reference to extrinsic evidence—admits of only “one reasonable interpretation.” *Brad H. v. City of New York*, 17 N.Y.3d 180, 185 (2011).

DSE deluges the Court with a mass of extrinsic evidence concerning purported “customs and practices of the pharmaceutical industry.” Opp. 11–17. This includes alleged “facts” about primary and secondary endpoints, the Study Protocol, the Study Record, and on and on. *Id.* None of this is relevant or can even be considered for purposes of this motion for judgment on the pleadings. Like all forms of extrinsic evidence, “evidence of custom or practice may be admissible only if the agreement is found to be ambiguous” in the first place. *Katel Ltd. Liab. Co. v. AT&T Corp.*, 607 F.3d 60, 66 (2d Cir. 2010) (internal quotation marks omitted). Such evidence “should not be admitted to *create* an ambiguity in an otherwise clear and unambiguous agreement,” *id.*, because “[a]mbiguity is determined by looking within the four corners of the document, not to outside sources,” *Dish Network Corp. v. Ace Am. Ins. Co.*, 21 F.4th 207, 211 (2d Cir. 2021) (internal quotation marks omitted). The only exception to this rule is when a contract uses a specialized term of art that “convey[s] no meaning to those who are not initiated into the mysteries of the craft.” *L. Debenture Tr. Co. of N.Y. v. Maverick Tube Corp.*, 595 F.3d 458, 466 (2d Cir. 2010) (internal citation omitted). But the Agreement contains no such term.

The Second Circuit takes a dim view of attempts to inject industry custom-and-practice evidence to muddy an unambiguous contract. *See, e.g., id.* at 469–71 (holding that undefined contractual term “common stock” is not ambiguous and rejecting “custom and usage” argument); *Orchard Hill Master Fund Ltd. v. SBA Commc’ns Corp.*, 830 F.3d 152, 160 (2d Cir. 2016) (rejecting “market convention” allegations given “the plain language and structure of” contracts).

DSE fails to identify any case in which a court relied on custom-and-practice evidence to

deem a contract ambiguous. In *Sompo Japan Ins. Co. of Am. v. Norfolk S. Ry. Co.*, the court ultimately declined “to consider evidence of industry practice and custom” because the plaintiff was attempting “to persuade” the court “to ignore the [the terms of the contract] not to help [it] interpret it.” 762 F.3d 165, 181 (2d Cir. 2014). In *Glob. Reinsurance Corp. of Am. v. Century Indem. Co.*, the court held that evidence of industry custom only “confirm[ed] what [was] apparent from the unambiguous language of the [insurance] certificates.” 22 F.4th 83, 100 (2d Cir. 2021). In *Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y.*, the court held the term “mandatory transfer” was not “self-reading” *before* it considered evidence about customs in the “credit derivatives trade.” 375 F.3d 168, 180 (2d Cir. 2004). In *Seven Star Shoe Co. v. Strictly Goodies, Inc.*, the court only considered “business usage” because the contract was ambiguous. 657 F. Supp. 917, 921 (S.D.N.Y. 1987). And in *Edison v. Viva Int’l*, only after finding the contract “ambiguous” did the court deem extrinsic evidence relevant. 70 A.D.2d 379, 383 (1st Dep’t 1979). In short, “evidence of trade usage and industry custom may not be introduced to contradict an express term of a contract.” *Wells Fargo Bank, N.A. v. HoldCo Asset Mgmt., L.P.*, 2017 WL 2963501, at *11 (S.D.N.Y. July 11, 2017).

DSE also urges the Court to consider extrinsic documents, including the “Study Protocol” and “Study Record,” as a way of interpreting the Agreement. These materials—most of which support *Esperion’s* reading of Section 9.2., *see infra* 8–9—cannot be considered. DSE notes the Agreement mentions the existence of a Study Protocol, but a mere mention does not incorporate the Study Protocol into the Agreement. *See Forge Underwriting Ltd. v. AmTrust Fin. Servs., Inc.*, 2023 WL 6890844, at *5 (S.D.N.Y. Oct. 19, 2023) (“fleeting reference” does not incorporate). Similarly, DSE notes the Agreement contains a press release with a link to the website where the Study Record is available, but that does not make the Study Record part of the Agreement. *See*

Whitestone Constr. Corp. v. Yuanda USA Corp., 2021 WL 5234395, at *8 (S.D.N.Y. Nov. 9, 2021) (incorporation requires “language incorporating the document [that] clearly communicates that the purpose of the reference is to incorporate the referenced material into the contract” (internal quotation marks omitted)). The Agreement has a merger clause, *see* Agmt. § 14.5, and “where a contract contains a merger clause,” extrinsic evidence cannot “vary or contradict the terms of the writing,” *ARS Kabirwala, LP v. El Paso Kabirwala Cayman Co.*, 2018 WL 2247203, at *5 (S.D.N.Y. May 15, 2018) (internal quotation marks omitted).

Because extrinsic evidence may not be considered, Esperion did not discuss the vast amount of extrinsic evidence confirming its reading is the correct one. Deposition testimony will show what DSE already admitted in its Answer: The parties knew the CLEAR Outcome Study would generate multiple results measuring cardiovascular risk reduction. Answer ¶ 28. During the negotiation and drafting of the Agreement, DSE proposed to condition the milestone payment on the specific MACE-4 endpoint. FAC ¶¶ 37–39; Answer ¶¶ 37–38. But Esperion expressly *rejected* that proposed contractual term, and the parties ultimately agreed that “a result”—i.e., any result showing cardiovascular risk reduction meeting the contractual thresholds—would trigger the payment obligation. FAC ¶¶ 40–42, 46; Answer ¶¶ 41, 46. Thus, even if the Court were to consider extrinsic evidence when interpreting the Agreement, it would confirm Esperion’s plain-language reading. But none of this outside evidence can be considered in this Rule 12(c) motion.

II. DSE’s Interpretation Is Not Reasonable And The Court Should Enforce The Plain Terms Of The Agreement.

Plain Language. Section 9.2 of the Agreement is unambiguous. DSE must pay if Esperion obtains regulatory approval for a drug that “includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below as *a* result of the CLEAR Outcome Study.” Agmt. § 9.2 (emphasis added). For more than a century, New York courts have held that

“use of the indefinite article . . . ‘a’” refers “to any one of” several possibilities. *Van Brunt v. Van Brunt*, 111 N.Y. 178, 185 (1888). So if one Study result meets the risk-reduction thresholds, and is reflected in the label, DSE must make the milestone payment. As DSE has admitted, the Study included multiple “results” that demonstrated “a reduced risk of certain cardiovascular events.” Answer ¶¶ 28, 54. “[W]hen parties set down their agreement in a clear, complete document, their writing should be enforced according to its terms,” *Vt. Teddy Bear Co. v. 538 Madison Realty Co.*, 1 N.Y.3d 470, 475 (2004) (alteration and citation omitted), and DSE must make the payment.

DSE has never put forward a reasonable contrary interpretation that is rooted in the text of Section 9.2. DSE urges the Court to read “Section 9.2’s . . . Payment” as triggered “only if the . . . Study demonstrates” sufficient reduction “for its primary endpoint (MACE-4).” Opp. 13–14. But Section 9.2 simply “does not use” any of “the[se] word[s].” *Katel Ltd. Liab. Co.*, 607 F.3d at 65. **It does not mention “MACE.” It does not mention “MACE-4.” It does not mention “primary endpoint.”** Nor does it define or restrict the meaning of “cardiovascular risk reduction” or “relative risk reduction.”

DSE ignores Esperion’s argument that the Agreement contains many provisions showing that when the parties meant to specify particular results from the Study, they knew how to do so. *See* Mot. 10–11. Section 7.2.1 refers to “key results”; Schedule 7.3 refers to “lowering of LDL-C” and “reduction in high sensitivity C-reactive protein,” and Schedule 2.1.1 refers to an “endpoint” of “absolute change in HbA1c as compared to placebo.” Yet when it came time to define the result or results that would trigger payment in Section 9.2, the parties did not include limiting language; instead, they referred broadly to “a result,” with no particularity or limitation. The parties knew the Study would generate many different results, and the English language affords drafters of contracts many ways to express specificity and limitation. But they did not do

so in Section 9.2, even though they included limiting language and specialized terms throughout the remainder of the Agreement. This is “strong evidence that the omission was intentional.” *Avon Co. v. Fareva Morton Grove, Inc.*, 2022 WL 2208156, at *6 (S.D.N.Y. June 21, 2022).

Two canons of construction support Esperion’s reading. The general-terms canon requires that general terms—such as “a result” or “relative risk reduction”—should be read generally. *See United States v. Weiss*, 52 F.4th 546, 552 (3d Cir. 2022); Antonin Scalia & Bryan Garner, *Reading Law: The Interpretation of Legal Texts* 101 (2012). DSE says this canon applies to “the general use of terms without qualifiers,” Opp. 22 n.7, but that is exactly the case here: “a result” and “relative risk reduction” are general terms that are not qualified in any way. The canon against superfluity also counsels against DSE’s interpretation. *See LaSalle Bank Nat. Ass’n v. Nomura Asset Cap. Corp.*, 424 F.3d 195, 206 (2d Cir. 2005). Section 9.2’s “payable only once” provision specifies that no matter how many different Study results demonstrate cardiovascular risk reduction above the contractual thresholds, DSE has to make only one payment. DSE’s argument that only the MACE-4 result could trigger payment would render this provision superfluous. To avoid this problem, DSE says there are multiple products that might generate a MACE-4 result that could trigger payment. But this does not avoid superfluity. Section 9.2 provides that only the “*first* Regulatory Approval in the DSE Territory of a Licensed Product” could trigger DSE’s payment obligation. Agmt. § 9.2 (emphasis added). So DSE’s invented multiple-products-triggering-multiple-payments scenario is impossible.

Extrinsic Evidence. DSE says the “Study Protocol,” a document not incorporated in the Agreement, “defined ‘MACE’ as MACE-4.” Opp. 6. But Section 9.2 does not mention MACE or MACE-4. If anything, the Study Protocol shows the parties knew how to use limiting language to particularize broader concepts, such as MACE, but chose not to do so in Section 9.2. DSE also

says the Study Protocol used the phrase “relative risk reduction” in reference to the MACE-4 endpoint, e.g., “14.3% relative risk reduction in the primary 4-component MACE endpoint.” Opp. 7 (emphasis added). But again, that the Study Protocol had to specify it meant relative risk reduction in “the primary 4-component MACE endpoint” proves that “relative risk reduction” in Section 9.2 is a general term that could apply to multiple Study results or endpoints. Here, too, the use of limiting language confirms the parties knew how to particularize broader concepts, such as “relative risk reduction,” but deliberately chose not to do so in Section 9.2.

DSE notes the “Study Record,” a different piece of extrinsic evidence, describes MACE-4 as the “primary outcome.” Opp. 14–15. But even if the Court were to consider the Study Record, and it should not, it has no bearing on the meaning of Section 9.2, let alone what endpoints the parties intended to include when they used the term “a result.” If the parties intended MACE-4 to be the only “outcome” constituting a “result” that could trigger payment, they would have said so in the Agreement. But the parties did not mention MACE, MACE-4, “primary outcome,” “primary endpoint,” or any other limiting language in Section 9.2.

DSE’s Other Arguments. DSE argues the phrase “the relative risk reduction rate” in Section 9.2 “confirm[s] that *one* relative risk reduction rate mattered for purposes of the milestone payment: the study’s primary endpoint.” Opp. 16. But as Esperion explained, *see* Mot. 14–15, DSE has distorted the phrase by ignoring the last two words. In full, it reads “the relative risk reduction rate *indicated below*.” Agmt. § 9.2 (emphasis added). That modifier—“indicated below”—makes clear that “the relative risk reduction rate indicated below” refers only to the contractual thresholds listed in the table at the bottom of Section 9.2. *See Great N. Ins. Co. v. Dayco Corp.*, 637 F. Supp. 765, 787 (S.D.N.Y. 1986) (phrase “the amount indicated below” refers to a number that immediately followed). These contractual thresholds—“Equal to or greater than

15% and less than 20%” and “Equal to or greater than 20%”—do not refer to any particular Study result and are open-ended “without any words of limitation.” *N.Y. State Nurses Ass’n Benefits Fund v. Nyack Hosp.*, 46 F.4th 97, 107 (2d Cir. 2022). DSE says this language “still supports the interpretation that only one relative risk reduction rate tied to the CLEAR Outcome Study matters.” Opp. 17. But as Esperion also explained, *see* Mot. 13, only one rate “matters” in the sense that the “milestone payment shall be payable only once,” Agmt. § 9.2. The key point is that nothing in Section 9.2 limits *which* of the many results could be a payment-triggering “result.”

DSE urges the Court to disregard the plain meaning of the words “a result,” arguing that they appear in an “idiom”—“as a result of.” Opp. 18–21. This is not persuasive. If the parties intended a causal relationship between one particular endpoint and the Study, they could have used the phrase “as *the* result of,” meaning “the sole cause of.” *See, e.g., Blackmon v. Bracken Constr. Co.*, 2019 WL 2344910, at *1 (M.D. La. June 3, 2019) (distinguishing between “as the result of” and “as a result of”). Moreover, even were the Court to adopt DSE’s strained reading—changing the phrase “as a result of” to “because of”—DSE’s rewrite would still fail. DSE’s payment obligation would be triggered when Esperion obtains approval “that includes cardiovascular risk reduction in the label that correlates with the relative risk reduction rate indicated below [because of] the CLEAR Outcome Study.” Agmt. § 9.2. Even with that revision, there is still nothing in Section 9.2 that limits the Payment to any one particular result among many.

CONCLUSION

The Court should enter declaratory judgment in Esperion’s favor, declaring that any result of the CLEAR Outcomes Study demonstrating cardiovascular risk reduction that meets the contractual thresholds satisfies the requirements of Section 9.2 of the Agreement to trigger DSE’s obligation to make the Payment to Esperion.

Dated: New York, New York
November 22, 2023

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